FDA Approved Products Developed with Technologies from the Intramural Research Program at the National Institutes of Health

Licensee	Product	FDA Approval Date / First Commercial U.S. Sale
Berlex Laboratories	Fludara®	18 April 1991 / 1991

- A DNA polymerase inhibitor (fludarabine) that has been shown to have potent activity in the treatment of B-cell leukemia. This compound is a cancer chemotherapeutic drug, 2-F-araA.

Bristol Myers Squibb	Videx®	09 Oct 1991 / 1991

- A treatment of HIV infection with ddI. Selectively inhibits the replication of HIV by interfering with a critical element known as reverse transcriptase. Because of being better tolerated or having a different pattern of toxicity than other treatments, patients may find it useful in either individual or combination treatment therapy.

Hoffmann LaRoche	Hivid®	19 Jun 1992 / 1992

- A treatment of HIV infection with ddC. Inhibits the replication of HIV by interfering with the critical enzyme reverse transcriptase. Patients find it useful in either individual or combination treatment therapy.

Bristol Myers Squibb	Taxol®	29 Dec 1992 / 1996

- An improved method for administering Taxol® (paclitaxel) has significantly improved the treatment of cancerous tumors, particularly advanced stage epithelial ovarian and breast cancers. Paclitaxel is a compound derived from the bark of the Western Yew tree.

MedImmune Inc.	NeuTrexin®	17 Dec 1993 / 1994

- A treatment using trimetrexate as an anti-parasitic agent for infection. Infections due to Toxoplasma gondii and Pneumocystis carinii, as seen in AIDS patients are extremely refractory to standard therapy can be effectively treated by administering this drug.

GlaxoSmithKline	Havrix®	22 Feb 1995 / 1997

- A vaccine from the isolation of Hepatitis A virus strain HM-175. Hepatitis A is probably the most widespread of viral hepatitis diseases and is an endemic childhood disease in the underdeveloped countries of the world.

Janssen Pharmaceuticals	SPORANOX® Oral Solution	21 Feb 1997 / 1997

- Oral formulation of the anti-fungal agent itraconazole that is used for the treatment of painful and debilitating fungal infections of the esophagus and mouth, commonly called thrush. Itraconazole is solubilized for this application through coupling with hydroxy-propyl-cyclodextrin, a molecular inclusion complex.

Protein Design Laboratory / Hoffman LaRoche	ZENAPAX®	10 Dec 1997 / 1998

- A humanized monoclonal antibody used for the prevention of acute kidney transplant rejection. This recombinantly produced antibody achieves its immunosuppressive properties by binding to the alpha (or Tac) subunit of human interleukin-2 (IL-2) receptor that is expressed on the surface of activated lymphocytes.

FDA Approved Products Developed with Technologies from the Intramural Research Program at the National Institutes of Health

Licensee	Product	FDA Approval Date / First Commercial U.S. Sale
MedImmune Inc.	Synagis®	19 Jun 1998 / 1998

- A monoclonal antibody used for the prevention and treatment of serious lower respiratory tract disease by respiratory syncytial virus (RSV). RSV is the most common cause of pneumonia and bronchiolitis in infancy and early childhood. Synagis is the world's first monoclonal antibody licensed by the FDA for any infectious disease.

Baxter Pharmaceuticals, formerly North American Vaccine, Inc.	Certiva™	29 Jul 1998 / 1998

- A combined diphtheria, tetanus and acellular pertussis vaccine for use in infants and children. A special process that reduces local and systemic adverse events commonly associated with traditional whole-cell DPT vaccine administration has detoxified the acellular pertussis component of this vaccine. Certiva™ is the first pediatric vaccine introduced into the U.S. market by a new independent vaccine producer in over ten years. (Manufacturer has withdrawn the product from the market)

Isis Pharmaceuticals Inc.	Vitravene®	26 Aug 1998 / 1998

- A phosphorothioate oligonucleotide that inhibits cytomeglovirus (CMV) infections in the eye. Such infections commonly occur in immunocompromised patients with resultant damage to the retina. Vitravene® is the first antisense therapeutic approved for use in humans.

Wyeth Laboratories Inc.	RotaShield®	31 Aug 1998 / 1998

- A live oral vaccine for the prevention of rotavirus gastroenteritis in infants. Rotavirus is the single most common cause of epidemic severe acute gastroenteritis (diarrhea and vomiting) in infants and children from both developed and developing countries. RotoShield® is the first rotavirus vaccine approved for use in humans. (Manufacturer has withdrawn the product from the market)

Berlex Laboratories, formerly Diatide Inc.	AcuTect®	14 Sep 1998 / 1998

- A synthetic peptide radiopharmaceutical used for the detection of acute deep venous thrombosis (DVT). DVT affects an estimated 5 million individuals in the U.S. each year and is the most common source of pulmonary embolism. AcuTect® is the first in-vivo imaging agent to target acute DVT in the lower extremities.

Genzyme Corp.	Thyrogen®	30 Nov 1998 / 1998

- A recombinant form of human thyroid stimulating hormone (TSH) for use in follow-up screening of patients who have been treated for thyroid cancer. Thyrogen® permits these patients to avoid the debilitating effects of thyroid hormone withdrawal while undergoing standard diagnostic procedures such as serum thyroglobulin testing and radioiodine imaging.

GlaxoSmithKline	LYMErix™	21 Dec 1998 / 1999

- The world's first vaccine for the prevention of Lyme disease. Lyme disease is one of the fastest vector-borne diseases in the US. It can lead to severe and debilitating problems such as arthritis, heart abnormalities and Bell's palsy. (Manufacturer has withdrawn the product from the market)

FDA Approved Products Developed with Technologies from the Intramural Research Program at the National Institutes of Health

Licensee	Product	FDA Approval Date / First Commercial U.S. Sale
Berlex Laboratories, formerly Diatide Inc.	NeoTect®	03 Aug 1999 / 1999

- A synthetic peptide radiopharmaceutical used for the diagnosis of lung cancer. The probe binds to somatostatin receptor-bearing masses in the lungs, and offers additional information to the physician. The procedure, being minimally invasive, carries much reduced risk compared to invasive procedures like biopsies. (Manufacturer has withdrawn the product from the market)

MedImmune Inc./ Biotrin International	Parvovirus B19 Enzyme Immunoassay	06 Aug 1999 / 2001

- By detecting B19 virus IgM antibodies in human serum and plasma, this product should be helpful in diagnosing and managing parvovirus B19 infection, which can put pregnant women at serious risk of fetal loss. This is the first diagnostic test for parvovirus B19 infection approved by the FDA for U.S. use.

GlaxoSmithKline	Twinrix®	11 May 2001 / 2001

- A vaccine formulation that combines both Hepatitis A and Hepatitis B. Combining the two vaccines, for two of the most common infectious diseases that represent serious public health problems, Twinrix® offers significant advantages such as increased convenience for patient and physician, fewer injections and greater compliance compared with two separate vaccines.

IDEC Pharmaceuticals	Zevalin®	19 Feb 2002 / 2002

- A treatment for non-Hodgkin's lymphoma, which affects 50,000 Americans annually. A majority of these cases are low-grade lymphomas that do not respond to other treatments. Treatment with Zevalin®, which is simple and fast, and has less severe side effects, is especially suited for these patients. This drug combines the targeting power of monoclonal antibodies with the cell killing ability of radioactive atoms, and is the first radioimmunotherapy to be approved by the FDA.

Millennium Pharmaceuticals	Velcade®	13 May 2003 / 2003

- A treatment for multiple myeloma, that works by specifically inhibiting an enzyme complex known as the proteosome. Under an accelerated approval program, the FDA has allowed the use of Velcade in patients who have failed two prior therapies. The selectivity and manageable side-effect profile of this boronic dipeptide compound makes it an exciting new cancer drug. NIH researchers made a critical contribution by developing stable, pharmaceutically acceptable compositions of these important compounds. Indeed, as the first proteosome inhibitor to be approved by the FDA, Velcade® opens the door for a new class of useful drugs.

Angiotech/Boston Scientific	TAXUS™ Express^{2}™ Monorail Paclitaxel-Eluting Coronary Stent System	04 Mar 2004 / 2004

- Treatment of coronary artery disease by balloon angioplasty and placement of a stent is often followed by restenosis caused by cellular proliferation. The TAXUS™ Express^{2}™ stent system contains two medical components: the Express^{2} coronary stent and paclitaxel contained in a polymer coating. NIH researchers discovered that the paclitaxel component inhibits cellular proliferation and subsequent restenosis thus leading to greatly improved medical outcomes.

FDA Approved Products Developed with Technologies from the Intramural Research Program at the National Institutes of Health

Licensee	Product	FDA Approval Date / First Commercial U.S. Sale
Barr Laboratories	Didanosine Delayed-Release Capsules	03 Dec 2004 /

- Generic equivalent for Videx® EC, a treatment of HIV infection with ddI. Selectively inhibits the replication of HIV by interfering with a critical element known as reverse transcriptase. Because of being better tolerated or having a different pattern of toxicity than other treatments, patients may find it useful in either individual or combination treatment therapy.

Amgen Inc.	Kepivance™	15 Dec 2004 /

- Kepivance™ (palifermin) is a human keratinocyte growth factor protein produced using recombinant DNA technology. It is used to decrease the incidence and duration of severe mouth sores in patients with hematologic cancers who receive myelotoxic therapy. In such a therapy, the patients' myeloid cells are first destroyed by chemotherapy alone or in combination with radiation, and then reconstituted with a bone marrow transplant. Kepivance™ is the first and only therapy to treat the severe mouth sores that afflict these patients as a painful and unavoidable side effect of the treatment.